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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/023,634	12/17/2001	Richard A. Shimkets	21402-221 (Cura 521)	4413

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EXAMINER
STEADMAN, DAVID J

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 09/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/023,634	SHIMKETS ET AL.	
	Examiner	Art Unit	
	David J Steadman	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-41 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-41 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of the Application

[1] Claims 1-41 are pending in the application.

[2] Applicant's amendment to the specification to add a sequence listing in Paper No. 4, filed June 28, 2002, is acknowledged.

[3] Receipt of information disclosure statements filed April 19, 2002 and April 02, 2003, is acknowledged.

[4] In the interest of expediting prosecution of the instant application, the examiner requests that applicant identify the provisional application(s) and sequence identifier for the elected sequence.

Election/Restrictions

[5] Restriction to *one* of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4, 29, and 32, drawn to an isolated polypeptide, a pharmaceutical composition, and a kit, classified in class 514, subclass 2.

II. Claims 5-14, 30, and 33, drawn to an isolated nucleic acid, a vector, a cell, a pharmaceutical composition, and a kit, classified in class 514, subclass 44.

III. Claims 15-17, 31, and 34, drawn to an antibody, a pharmaceutical composition, and a kit, classified in class 530, subclass 387.9.

IV. Claim 18, drawn to a method for determining the presence or amount of a polypeptide, classified in class 435, subclass 7.1.

V. Claim 19, drawn to a method for determining the presence or amount of a nucleic acid, classified in class 435, subclass 6.

VI. Claim 20, drawn to a method of identifying an agent that binds to a polypeptide, classified in class 435, subclass 7.1.

VII. Claim 21, drawn to a method of identifying an agent that binds to a polypeptide, classified in class 435, subclass 7.1.

VIII. Claim 22, drawn to a method for modulating the activity of a polypeptide, classified in class 530, subclass 350.

IX. Claims 23-24 and 40, drawn to a method of treating or preventing a disorder by administering a polypeptide, classified in class 514, subclass 2.

X. Claims 25-26, drawn to a method of treating or preventing a disorder by administering a polynucleotide, classified in class 514, subclass 44.

XI. Claims 27-28 and 41, drawn to a method of treating or preventing a pathology by administering an antibody, classified in class 424, subclass 130.1.

XII. Claim 35, drawn to the use of a therapeutic in the manufacture of a medicament, wherein said therapeutic is a polypeptide, classified in class 514, subclass 2.

XIII. Claim 35, drawn to the use of a therapeutic in the manufacture of a medicament, wherein said therapeutic is a nucleic acid, classified in class 514, subclass 44.

XIV. Claim 35, drawn to the use of a therapeutic in the manufacture of a medicament, wherein said therapeutic is an antibody, classified in class 424, subclass 130.1.

XV. Claims 36-37, drawn to a method for screening for a modulator of activity or of latency or predisposition to a disorder, classified in class 435, subclass 7.1.

XVI. Claim 38, drawn a method for determining the presence of or predisposition to a disease associated with altered levels of a polypeptide, classified in class 435, subclass 7.1.

XVII. Claim 39, drawn a method for determining the presence of or predisposition to a disease associated with altered levels of a nucleic acid, classified in class 435, subclass 6.

[6] If applicant should elect the invention of Group I, VI, VII, VIII, IX, XII, XV, or XVI, restriction to *one* of the following is also required under 35 USC 121.

a) The polypeptide of SEQ ID NO:2.

b) The polypeptide of SEQ ID NO:4.

c) The polypeptide of SEQ ID NO:6.

d) The polypeptide of SEQ ID NO:8.

e) The polypeptide of SEQ ID NO:10.

f) The polypeptide of SEQ ID NO:12.

g) The polypeptide of SEQ ID NO:14.

h) The polypeptide of SEQ ID NO:16.

i) The polypeptide of SEQ ID NO:18.

j) The polypeptide of SEQ ID NO:20.

k) The polypeptide of SEQ ID NO:22.

l) The polypeptide of SEQ ID NO:24.

m) The polypeptide of SEQ ID NO:26.

n) The polypeptide of SEQ ID NO:28.

o) The polypeptide of SEQ ID NO:30.

p) The polypeptide of SEQ ID NO:32.

q) The polypeptide of SEQ ID NO:34.

r) The polypeptide of SEQ ID NO:36.

s) The polypeptide of SEQ ID NO:38.

t) The polypeptide of SEQ ID NO:40.

u) The polypeptide of SEQ ID NO:42.

[7] If applicant should elect the invention of Group III, IV, XI, or XIV, restriction to *one* of the following is also required under 35 USC 121.

v) An antibody that binds the polypeptide of SEQ ID NO:2.

w) An antibody that binds the polypeptide of SEQ ID NO:4.

x) An antibody that binds the polypeptide of SEQ ID NO:6.

y) An antibody that binds the polypeptide of SEQ ID NO:8.

z) An antibody that binds the polypeptide of SEQ ID NO:10.

aa) An antibody that binds the polypeptide of SEQ ID NO:12.

bb) An antibody that binds the polypeptide of SEQ ID NO:14.

cc) An antibody that binds the polypeptide of SEQ ID NO:16.

dd) An antibody that binds the polypeptide of SEQ ID NO:18.

ee) An antibody that binds the polypeptide of SEQ ID NO:20.

ff) An antibody that binds the polypeptide of SEQ ID NO:22.

gg) An antibody that binds the polypeptide of SEQ ID NO:24.

hh) An antibody that binds the polypeptide of SEQ ID NO:26.

ii) An antibody that binds the polypeptide of SEQ ID NO:28.

jj) An antibody that binds the polypeptide of SEQ ID NO:30.

kk) An antibody that binds the polypeptide of SEQ ID NO:32.

ll) An antibody that binds the polypeptide of SEQ ID NO:34.

mm) An antibody that binds the polypeptide of SEQ ID NO:36.

nn) An antibody that binds the polypeptide of SEQ ID NO:38.

oo) An antibody that binds the polypeptide of SEQ ID NO:40.

pp) An antibody that binds the polypeptide of SEQ ID NO:42.

[8] If applicant should elect the invention of Group II, V, X, XIII, or XVII, restriction to *one* of the following is also required under 35 USC 121.

qq) A polynucleotide encoding SEQ ID NO:2 including SEQ ID NO:1.

rr) A polynucleotide encoding SEQ ID NO:4 including SEQ ID NO:3.

ss) A polynucleotide encoding SEQ ID NO:6 including SEQ ID NO:5.

tt) A polynucleotide encoding SEQ ID NO:8 including SEQ ID NO:7.

uu) A polynucleotide encoding SEQ ID NO:10 including SEQ ID NO:9.

vv) A polynucleotide encoding SEQ ID NO:12 including SEQ ID NO:11.

ww) A polynucleotide encoding SEQ ID NO:14 including SEQ ID NO:13.

xx) A polynucleotide encoding SEQ ID NO:16 including SEQ ID NO:15.

yy) A polynucleotide encoding SEQ ID NO:18 including SEQ ID NO:17.

zz) A polynucleotide encoding SEQ ID NO:20 including SEQ ID NO:19.

aaa) A polynucleotide encoding SEQ ID NO:22 including SEQ ID NO:21.

bbb) A polynucleotide encoding SEQ ID NO:24 including SEQ ID NO:23.

ccc) A polynucleotide encoding SEQ ID NO:26 including SEQ ID NO:25.

ddd) A polynucleotide encoding SEQ ID NO:28 including SEQ ID NO:27.

eee) A polynucleotide encoding SEQ ID NO:30 including SEQ ID NO:29.

fff) A polynucleotide encoding SEQ ID NO:32 including SEQ ID NO:31.

ggg) A polynucleotide encoding SEQ ID NO:34 including SEQ ID NO:33.

hhh) A polynucleotide encoding SEQ ID NO:36 including SEQ ID NO:35.

iii) A polynucleotide encoding SEQ ID NO:38 including SEQ ID NO:37.

jjj) A polynucleotide encoding SEQ ID NO:40 including SEQ ID NO:39.

kkk) A polynucleotide encoding SEQ ID NO:42 including SEQ ID NO:41.

[9] The inventions are distinct, each from the other because:

[10] The polypeptides of Groups a)-u), the antibodies of Groups v)-pp), and the polynucleotides of Groups qq)-kkk) are structurally distinct and no single polypeptide of Groups a)-u), antibody of Groups v)-pp), or polynucleotide of Groups qq)-kkk) would render any of the others obvious to one of ordinary skill in the art.

[11] The polypeptide of Group I, the nucleic acid of Group II, and the antibody of Group III each comprises a chemically unrelated structure capable of separate manufacture, use and effect. The polynucleotide of Group II has other utility besides encoding polypeptides such as being used as a hybridization probe and the polypeptide of Group I can be made by another method such as purification from the natural source or chemical synthesis.

[12] The polypeptide of Group I is unrelated to the method(s) of Groups IV, V, X, XI, XIII, XIV, and XVII as it is neither used nor made by the method(s) of Groups IV, V, X, XI, XIII, XIV, and XVII.

[13] The polypeptide of Group I and the methods of Groups VI, VII, VIII, IX, XII, XV, and XVI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another

materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide of Group II can be used as an antigen in the production of antibodies.

[14] The polynucleotide of Group II is unrelated to the method(s) of Groups IV, VI, IX, XI, XII, XIV, XV, and XVI as it is neither used nor made by the method(s) of Groups IV, VI, IX, XI, XII, XIV, XV, and XVI.

[15] The polynucleotide of Group II and the methods of Groups V, VII, VIII, X, XIII, and XVII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotide of Group I can be used for protein expression.

[16] The antibody of Group III is unrelated to the method(s) of Groups V, VI, VII, VIII, IX, X, XII, XIII, XV, XVI, and XVII as it is neither used nor made by the method(s) of Groups V, VI, VII, VIII, IX, X, XII, XIII, XV, XVI, and XVII.

[17] The antibody of Group III and the methods of Groups IV, XI, and XIV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Group III can be used as an affinity reagent in the purification of a polypeptide.

[18] The methods of Groups IV-XVII are independent as they comprise different steps, utilize different products and yield different results.

[19] MPEP § 803 sets forth two criteria for a proper restriction between patentably distinct inventions: (A) The inventions must be independent or distinct as claimed and (B) There must be a serious burden on the examiner. As shown above, each of the inventions of Groups a)-kkk) and I-XVII are independent

or distinct, thus satisfying the first criterion for a proper restriction. MPEP § 803 additionally states that a serious burden on the examiner may be prima facie shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search. Each of the inventions requires a separate patent and non-patent literature search requiring a different text and/or sequence search for each Group and thus, co-examination of the inventions of Groups a)-kkk) and I-XVII would be a serious burden on the examiner.

[20] It is noted that claims 1-41 will be examined only to the extent the claims read on the elected subject matter.

[21] Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

[22] Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (703) 308-3934. The Examiner can normally be reached Monday-Friday from 7:00 am to 5:00 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX number for submission of official papers to Group 1600 is (703) 308-4242. Draft or informal FAX communications should be directed to (703) 746-5078. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

David J. Steadman
Patent Examiner
Art Unit 1652

09/22/03